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| 10/789,433 | 02/27/2004 | Mark Thomas Muldoon | 19596-0571<br>(45738-296417) | 5696 |

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| EXAMINER | |
|---|---|
| HINES, JANA A | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/789,433 | MULDOON ET AL. | |
| | Examiner | Art Unit | |
| | JaNa Hines | 1645 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *19 November 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *10-13 and 15-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-13 and 15-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## *DETAILED ACTION*

### *Amendment Entry*

1. The amendment filed November 19, 2009 has been entered. Claims 10, 15 and 16 have been amended. Claims 1-9, 14 and 18-20 are cancelled. Claims 10-13 and 15-17 and SEQ ID NO:2 are under consideration in this Office Action.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 10-13 and 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al., (Meat Science. 2002. Vol. 61:55-60, available on online December 21, 2001) in view of Sheng et al (J. of Bio. Chem. 1992. Vol. 367(35): 25,407-25,413).

Claim 10 is drawn to an assay for detecting a mammalian troponin molecule in animal feed, the assay comprising: a) extracting the mammalian troponin molecule from the animal feed to form an animal feed extract; b) reacting the animal feed extract with a ligand that is specific for the mammalian troponin molecule and not specific for an avian troponin molecule for a time and under conditions sufficient to form a complex between the ligand and the troponin molecule; and c) detecting the complex either directly or

indirectly as a measure of the presence or amount of the troponin molecule in the animal feed and wherein the ligand reacts with or binds to an amino acid sequence SEQ ID NO:2 and wherein the presence of the mammalian troponin molecule in the animal feed extract indicates the presence of the mammalian troponin molecule in the animal feed.

Claim 11 is drawn to the mammalian troponin molecule is a troponin I molecule. Claim 12 is drawn to the mammalian troponin molecule is a troponin I molecule is a fast twitch skeletal muscle troponin I molecule. Claim 13 is drawn to the ligand being an antibody and the troponin molecule being a polypeptide. Claim 15 is drawn to the ligand binds to a peptide having an amino acid of SEQ ID NO: 2. Claim 16 is drawn to the ligand binds to a peptide having an amino acid sequence selected from the group consisting of SEQ ID NO: 2. Claim 17 is drawn the ligand being specific for an equine troponin I protein, a porcine troponin I protein or a bovine troponin I protein.

Chen et al., teach immunological methods for detecting the porcine troponin I wherein immunoblotting was performed using isolated proteins detected by a monoclonal antibody (page 56, col.2). Chen et al., teach an indirect ELISA using the monoclonal antibody as the detection reagent for detecting porcine skeletal troponin I (sTnI) (page 57, col.1). Figure 2 shows the result of detecting porcine sTnI in a sample for a time and under conditions sufficient to form a complex between the ligand and the troponin; and indirectly detecting the complex as a measure of the presence or amount of the troponin molecule in the sample. Chen et al., teach the specificity of the monoclonal antibody which recognized porcine sTnI but not other troponin molecules from chicken (page 58, col.2). Chen et al., teach the production of monoclonal

antibodies from immunized mice (page 56, col.2). The samples were raw and cooked porcine muscle extracts (page 56, col. 1-2) to thereby form the animal feed extract. It is noted that the specification at page 5, lines 6-11 teach that the term "animal feed" refers to any substance provided to an animal for nourishment, including preparations from meat products from animals for human consumption. Therefore the use of raw and cooked porcine muscle samples, meets the limitation drawn to animal feed and animal feed extract.

Chen et al., teach that several specific monoclonal antibodies have been raised to provide a consistent and continuous supply of immunoreagents for routine immunoassays for the detection of bovine, porcine and chicken adulteration in meat mixtures (page 55, col.1). Chen et al., teach it is important to reveal the identity and specific antigenicity of the skeletal muscle troponin from several other species for the development of species-specific antibodies (page 55, col.2). Chen et al., teach the recognition and use of monoclonal antibodies as specific for sTnI and demonstrated the heterogeneity of sTnI is differentiated immunologically with antibodies at the species level (page 56, col.1). Chen et al., teach sTnI is an ideal species marker for immunoassays for the detection of species origins in the meats of severely heat-processed commodities (page 60, col.1). However Chen et al., do not explicitly teach a ligand that reacts with or binds to SEQ ID NO:2.

Sheng et al., teach assay for detecting a mammalian skeletal muscle, the polypeptide or cDNA troponin I (TnI) molecule in a lysate sample, by western blotting whereby the sample contains a skeletal monoclonal antibody ligand specific for troponin I having SEQ ID NO:2 to form a complex between the antibody and troponin I; and detecting the complex as a measure of the presence of the troponin I (Figure 3). In Figure 3, Sheng et al., show an immunoblot result and detection of TnI with a

monoclonal antibody. Sheng et al., teach skeletal muscle cDNA clone for troponin I and encoding rabbit fast twitch skeletal muscle TnI (page 25, 408, col.1). Sheng et al., teach the cDNA and the deduced amino acid sequence of rabbit fast skeletal muscle TnI in Figure 1 and the nucleotide sequence homology of rabbit and mouse TnI in Figure 2. Sheng et al., teach monoclonal antibodies that react with or binds to SEQ ID NO:2. Furthermore Sheng et al., teach the production of the TnI monoclonal antibody which include a monoclonal antibody produced by immunizing an animal with the peptide having SEQ ID NO:2 (page 25,409, col. 2). Sheng et al., also teach a ligand that binds to SEQ ID NO:2; and a ligand that binds to a nucleic acid molecule encoding a peptide having the amino acid sequence of SEQ ID NO:2.

Therefore it would have been prima facie obvious at the time of applicants' invention to apply the ligand that reacts with or binds to an amino acid sequence selected from the group consisting of SEQ ID NO:2 of Sheng et al, to the assay for detecting a mammalian troponin molecule in a sample as taught by Chen et al., in order to provide a consistent and continuous supply of immunoreagents for routine immunoassays for the detection of species adulteration. One of ordinary skill in the art would have a reasonable expectation of success by exchanging the monoclonal antibody ligand of Chen et al., for the monoclonal antibody ligand of Sheng et al., which reacts with and/or binds to SEQ ID NO:2 because Chen et al., teach the desire to have specific troponin species marker for detection immunoassays. Furthermore, no more than routine skill would have been required to exchange the ligand of Chen et al., for the available ligand of Sheng et al., since Chen et al., teach the desire to have a variety of mammalian troponin ligands, like the ligand of Sheng et al., that selectively bind SEQ ID NO:2 or rabbit troponin and have the ability to not be specific for avian troponin molecules. Finally it would have been prima facie obvious to combine the invention of

Chen et al., and Sheng et al., to advantageously achieve the detection of mammalian troponin in adulterated meat samples since all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

### *Response to Arguments*

3. Applicant's arguments filed November 19, 2009 have been fully considered but they are not persuasive.

Applicants respectfully submit that the claims are directed to methods of detecting mammalian troponin molecules in an animal feed extract using an antibody that recognizes a troponin molecule from at least two mammalian species, but not a molecule from an avian species.

Chen et al., teach high homology existing between mammalians, essential binding and highly conserved regions. Sheng et al., also teach high homology between rabbit and mouse ligands, thereby meeting the limitation that the ligand is specific for at least 2 species. Sheng et al., even shows a comparison of those regions, while the prior art teach homology between small mammals such as rabbit and mice. Thus, an antibody is specific for an epitope, in whatever species that epitope is found. Therefore in view of the well known high degree of sequence homology and epitope binding ability of the antibodies, that the antibody would specific for at lest two species. Furthermore,

the antibody is ligand is produced by immunizing an animal with troponin I, see the instant specification at page 7, lines 21-27. Chen et al., teach the same immunization procedures. Additionally, Sheng et al., teach producing a rabbit antibody. Therefore, as previous stated, no more than routine skill is required to produce an antibody (ligand) from well known skeletal rabbit muscle troponin I, which binds to a peptide have SEQ ID NO:2, that is also specific for a mammalian troponin molecule from at least 2 mammalian species.

In this case, the claims require a peptide having an amino acid sequence selected from the group consisting of SEQ ID NO:2; Sheng et al., disclose SEQ ID NO:2. The claims require a ligand that is an antibody produced by immunizing an animal with a peptide having SEQ ID NO:2. Chen et al., teach the production of antibodies by immunizing mice with skeletal muscle troponin I. Sheng et al., teach SEQ ID NO:2 which is a skeletal muscle troponin I molecule. Therefore if Applicants antibody to SEQ ID NO:2 is specific for at least two species, then the teaching of SEQ ID NO:2 and the production of antibodies as taught by the prior art would clearly have those same abilities.

Applicants argue that the MT1 antibody is capable of differentiating between mammalian and avian species. In response to applicant's argument that the references fail to show the MT1 antibody of applicant's invention, it is noted that the features upon which applicant relies i.e., the MT1 antibody are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26

USPQ2d 1057 (Fed. Cir. 1993). Therefore the arguments about the ability of the MT1 antibody are not persuasive.

With respect to Applicants argument that the instant ligand is specific for a mammalian troponin molecule from at least two species; it is the position of the Office that "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342,1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). In *re re Crish*, 393 F.3d 1253, 1258, 73 USPQ2d 1364,1368 (Fed. Cir. 2004), the court stated that "just as the discovery of properties of a known material does not make it novel, the identification and characterization of a prior art material also does not make it novel." Furthermore, there is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference. *Schering Corp. v. Geneva Pharm. Inc.*, 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003). In this case, Sheng et al., disclose a peptide having SEQ ID NO:2. Therefore the peptide having SEQ ID NO:2 has the same abilities as the instantly claimed peptide having SEQ ID NO: 2. Immunizing an animal with identical peptides will produce an antibody specific for a molecule from at least two species and not specific to an avian molecule, just as it does within the instant specification.

Applicant has provided no evidence to the contrary. Chen et al., teach high homology existing between mammalians, essential binding and highly conserved regions. Sheng et al., also teach high homology between rabbit and mouse ligands, thereby meeting the limitation that the ligand is specific for at least 2 species. Sheng et al., even shows a comparison of those regions, while the prior art teach homology between small mammals such as rabbit and mice.

Applicants' assert that Chen et al., in view of Sheng et al., need to recite that the identical amino acid sequences have the ability to detect troponin molecules from at least two mammalian species and not detect the avian molecules. It is noted that Chen et al., in view of Sheng et al., recite producing an antibody by immunizing an animal with a peptide having SEQ ID NO:2, and reacting the antibody ligand with animal feed extract and detecting the complex. The rejection is maintained because the prior art peptide is identical to the instantly claimed peptide. The prior art references teach how to produce the ligand, i.e., by immunization of an animal to produce antibodies. Therefore the fact that the prior art is silent as the inherent characteristics of the produced ligand claimed in terms of a function, property or characteristic not explicitly disclosed by the reference, is not persuasive because one of ordinary skill in the art would have a reasonable expectation of success by exchanging the troponin peptides of Chen et al., for the troponin peptide of Sheng et al., which has SEQ ID NO:2 because Chen et al., teach the desire to have mammalian troponin species markers which do not detect avian troponin for detection immunoassays. Furthermore, Sheng et al., even finds higher levels of homology between rabbit and mouse nucleotide and amino acids sequences. Therefore applicants' argument is not persuasive.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, no more than routine skill would have been required to exchange the antibody ligand of Chen et al., for the available peptide of Sheng et al., since Chen et al., teach the desire to have a variety of mammalian troponin ligands along with immunization of peptides to procedure antibodies when all the claimed elements were known in the prior art and one skilled in the art could have combined and exchanged the peptides and ligands as claimed by known methods with no change in their respective functions and the combination would have been yielded predictable to one of ordinary skill in the art at the time of the invention.

Applicants argue that the Office has not provided an apparent reason to combine the teachings of Chen and Sheng et al. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. The Office has set forth multiple rationales to support the conclusion of obviousness. For instance, a reasonable expectation of

success has been shown. In this case, the rationale to support a conclusion that a claim would have been obvious is that all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded nothing more than predictable results to one of ordinary skill in the art. *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398, 127 S. Ct. 1727(2007).

Furthermore, the Office set forth that some degree of predictability is shown. In this case, the claims would have been obvious because the substitution of a similar or equivalent yet alternative mammalian skeletal muscle troponin I for another would have yielded predictable results to one of ordinary skill in the art at the time of the invention. Additionally, modifying the antibody production using the troponin I peptide of Chen et al., for a peptide having SEQ ID NO:2 was recognized as part of the ordinary capabilities of one skilled in the art while advantageously improving species identification immunoassays; especially when Chen et al., specifically states the desire to have species marker antigens (peptides) that would substantially increase the chance of eliciting specific antibodies. Thus predictability and a reasonable expectation of success was clearly set forth, therefore applicants arguments are not persuasive.

All the claimed elements were known in the prior art, and Applicants do not dispute this fact. Therefore, one skilled in the art could have exchanged the peptide as claimed and produced antibodies by immunization techniques by use in the detection assay with no change in their respective functions, and the substitution would have yielded not only predictable results to one of ordinary skill in the art at the time of the invention but also simplified the detection assay in a predictable manner.

Applicants' urge that the teachings of Chen et al., provide no reasonable expectation of success or motivation to use the amino acid sequence of troponin I from any other species to generate antibodies that recognize troponin I from more than one species. In this case, it would have been prima facie obvious to modify the invention of Chen et al., and Sheng et al., to advantageously detect mammalian troponin in adulterated meat samples since all the claimed elements were known in the prior art and one skilled in the art could have substituted the elements as claimed by known methods with no change in their respective functions, and the substitution would have yielded predictable results to one of ordinary skill in the art at the time of the invention. Furthermore, Chen et al., state that the selected markers are indispensable in developing immunoassays for the detection of species origins in animal feed.

Applicants assert that neither Chen et al. nor Sheng et al. teach or remotely suggest methods for detecting mammalian byproducts in an animal feed extract. Chen et al., teach immunological methods for detecting the troponin I with an antibody from samples of raw and cooked muscle extracts. It is noted that the specification at page 5, lines 6-11 teach that the term "animal feed" refers to any substance provided to an animal for nourishment, including preparations from meat products from animals for human consumption. Therefore the use of raw and cooked muscle samples, meets the limitation drawn to animal feed and animal feed extract, contrary to applicants statement.

Applicants argue that Chen *et al.* do not teach or suggest methods for using the antibody for porcine troponin to detect mammalian byproducts in an animal feed extract.

Chen et al., teach an indirect ELISA using antibodies as the detection ligand for detecting porcine skeletal troponin I in animal feed extract (meat products from animals for human consumption); contrary to applicants argument. Figure 2 shows the result of detecting porcine sTnI in a sample for a time and under conditions sufficient to form a complex between the ligand and the troponin; and indirectly detecting the complex as a measure of the presence or amount of the troponin molecule in the sample.

Thus, applicants' arguments are not persuasive and the rejection is maintained.

***Conclusion***

4. No claims allowed.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached Monday thru Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Robert Mondesi, can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/JaNa Hines/

Examiner, Art Unit 1645

/Mark Navarro/

Primary Examiner, Art Unit 1645